Photon™ DR Implantable Cardioverter Defibrillator

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Photon Implantable Cardioverter Defibrillator
Manufacturer: St. Jude Medical
Address: 701 E. Evelyn Ave., Sunnyvale, CA 94086
Approval Date: October 27, 2000
Approval Letter: http://www.fda.gov/cdrh/pdf/p910023s47a.pdf

What is it? This St. Jude implantable cardioverter/defibrillator (ICD) is a system that can detect different abnormally fast ventricular heart rhythms (tachyarrhythmias) and deliver an appropriate shock to restore a more normal heart rhythm. It can also detect and adjust for an abnormally slow heart rate in both the upper (atrial), as well as the lower (ventricular) heart chambers.

How does it work? The pulse generator (a metal can that is implanted in either the chest or the abdominal regions) is an electronic device that has a small computer which monitors the heart's rhythm and automatically treats the abnormal rhythm when it occurs. It can deliver pulses (electrical stimulus or shocks),which are programmed responses appropriate for the specific abnormal rhythm based on an analysis of the heart's electrical signals. Also, the generator can receive, store, and transmit information to the programmer (a non-implantable device of the ICD system).

When is it used? The pulse generator is intended for use in patients with a history of illness from an abnormal heart rhythm that originates in the lower chambers of the heart (ventricular tachyarrhythmias). These patients' hearts may have stopped (cardiac arrest) without having a heart attack or they may have an abnormally fast heart rate originating in a ventricle. In addition, the pulse generator can be used in patients whose primary therapy for significant chronic ventricular tachyarrythmias is corrective pacing in which the generator has the ability to provide high energy shocks if the arrhythmia worsens.

What will it accomplish? It will monitor and regulate a patient's heart rate by providing therapeutic shocks for abnormal heart rhythm originating in the ventricle(s) and pacing for both the atrial and the ventricular heart chambers for an excessively slow heart rate. This provides the patient with a more normal heart rate.

When should it not be used? The pulse generator system should not be used for ventricular tachyarrhythmias resulting from temporary or correctable factors such as drug effects, electrolyte imbalance, or acute heart attack.

Additional information: Summary of Safety and Effectiveness is available at: http://www.fda.gov/cdrh/pdf/p910023s47.html **Other:** http://www.americanheart.org